

# Hawai'i Department of Health Newborn Metabolic Screening Program

## Informed Consent for Supplemental Testing Research Study

### Participation, Purpose, and Procedures

You are being asked to participate in a research project conducted by the Hawai'i Department of Health to evaluate additional newborn screening tests for metabolic disorders. This supplemental testing will use the same blood specimen that has already been drawn for the mandated newborn screening tests. No additional blood from your baby will be needed. There is no additional cost to you for the supplemental testing.

### Description of Risks

Reporting of unusual results for supplemental testing may be delayed because the mandated newborn screening testing is done first. However, your baby's physician will be notified if the specimen is unsuitable for supplemental testing or if there are unusual results requiring further follow-up. Your baby's physician will discuss these results with you. If you are contacted, your baby will be referred to a doctor who specializes in the treatment of metabolic disorders. An unusual result does not always mean that a disorder is present. (About 90% of babies with unusual results will not have any of these disorders.) There is a small chance that these rare disorders could be missed by this test. If the specimen collected from the baby is found to be unsuitable for testing, the research testing will not be done.

### Description of Benefits

If you agree to participate in this research project, and your baby is found to have one of these disorders, early detection and treatment may prevent serious physical and mental disabilities, or even death.

There could be disorders identified by the study which may not cause significant health problems or require treatment. There may also be disorders identified for which there is no effective treatment.

By participating in the study, you are helping the Hawai'i Newborn Metabolic Screening Program decide which disorders to add to mandated newborn screening in the future. This will benefit future newborns with these disorders.

### Compensation

You will not receive any compensation to participate in this project. If a disorder is diagnosed, the cost of treatment will be the responsibility of the family.

### Confidentiality of Records

If you decide to participate in this research project, your physician will be notified that your baby's specimen was sent to California for supplemental testing. Participation in this research project also means consenting to the release of your baby's demographic information (for example, sex, birth date, birth weight, ethnicity), necessary for supplemental testing and follow-up, to the Hawai'i Department of Health. You might be contacted directly for some of this information if it is not available elsewhere. All information collected shall be confidential and shall not be released to anyone without your written permission.

### Injury

Your baby will experience no additional physical discomfort beyond the heel stick normally done for mandated newborn screening.

### Questions

For any questions on this research project, you may contact Christine Matsumoto, R.N., M.P.H., Newborn Metabolic Screening Program Coordinator, at (808) 733-9069, 741 Sunset Avenue, Honolulu, HI 96816.

### Voluntary Participation

Your participation in this research study is voluntary, and if you decide not to participate at any time, you will not lose any existing benefits or services. Your baby will still receive mandated newborn screening.

### Alternatives

If you do not wish to participate in this project but wish to have supplemental screening through a private laboratory, your doctor, the hospital staff, or the Newborn Metabolic Screening Program can assist you. There is a cost to you for supplemental screening through a private laboratory.

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### Consent

I have received information about the Supplemental Testing Research Study and I have read or had read to me this consent form. My questions were answered to my satisfaction.

☒ **Yes, I want my baby to participate  
in this research study**

**Yes**

**Baby's Name** \_\_\_\_\_

**Birth Date** \_\_\_\_\_

**Parent Signature** \_\_\_\_\_

**Date** \_\_\_\_\_

**Witness (optional)** \_\_\_\_\_

**Date** \_\_\_\_\_